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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,459	09/30/2003	Shuqi Chen	IQA-004.02	2458
25181	7590	06/29/2004	EXAMINER	
FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			SIEFKE, SAMUEL P	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/605,459	CHEN, SHUQI	
	Examiner	Art Unit	
	Samuel P Siefke	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, drawn to a multilayer column, classified in class 422, subclass 60.
- II. Claims 20-21, drawn to a method of manufacturing a multilayer column, classified in class 436, subclass 535.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group II and Group I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process. Placing the sheets of a membrane in a column and then adding analyte solution to the column, which binds to the membrane, then wash off extra, then run sample through column.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Scott Kamhlz on June 21, 2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-19. Affirmation of this election must be made by applicant in replying to this

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Office action. Claims 20 and 21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **1-3,10,11,14-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0139373 A (Univ. California) in view of Swanson et al. (USPN 5,073,484).

EP 0139373 teaches an assay device and immunoassay that comprises:

- a multi-layer column having a chamber with a first end having a first aperture;
- a plurality of vertically stacked membrane layers stacked within the chamber with solid-phase substrates each carrying a different anti-analyte (page 7, lines 9-20; fig. 2);
- membrane layers which are substantially planar (page 7, lines 9-20; fig. 2);
- planes of the membrane layers perpendicular to the longitudinal axis of the chamber (page 7, lines 9-20; fig. 1 and 2);

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- membrane layers comprising either filter-like microporous membrane or fiber matrix membrane (claim 14);
- membrane layers that are substantially transparent to light (page 11, line 12 – line 29; fig. 2,3);
- membrane layers which are filter layers having pores sized to substantially prevent flow of particles of a preselected size to central membrane layers (page 8, line 17 – page 9, line 14);
- membrane layers being axially spaced from one another along the longitudinal axis (page 8, line 29 – page 9, line 3);
- membrane layers which are planar, where the planes of the membrane layers are oriented at an oblique angle with respect to the longitudinal axis (page 8, line 29 – page 9, line 3);
- the chamber having a second aperture at a second end thereof (fig. 2);
- a fluid flow port providing a fluid exit flow path from within the chamber (fig. 2);
- membrane layers which are disposed on a planar substrate, the plane of the planar substrate being substantially parallel to the longitudinal axis of the chamber (claim 18);
- anti-analytes selected from the group consisting of antibodies, antigens, ligands, ligand receptors, etc.

EP 0139373 does not teach a multi-layer column that comprises: each of the membrane layers sized to occupy substantially all of the cross-section of the chamber

and the membrane layers engaging the wall of the chamber to inhibit the fluid sample from passing between the membrane layers and the wall of the chamber.

Swanson teaches an apparatus for the quantitative determination of an analyte in a liquid that employs a column containing a liquid-permeable solid medium defining a liquid flow path sized to occupy substantially all of the cross-section of the column and membrane layers engaging with the side of the wall of the column to prevent the fluid sample from passing between the solid medium and the wall of the chamber. Swanson also teaches a second embodiment (fig. 2 and 3) which is a multilayered filter paper within a plastic holder. The filter paper is placed in the holder so that each edge touches the inside wall of the holder. Sample is applied to the paper through a wick touching the end of the paper which forces the sample only through the paper. Therefore it would have been obvious to one having an ordinary skill in the art at the time the invention was made to modify EP '373 to include the membrane orientation of Swanson in order to have greater contact area in order to provide for better sensitivity.

Claims **4-7** are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0139373 A (Univ. California) in view of Swanson et al. (USPN 5,073,484) as applied to claim **1-3,16-19** above, and further in view of Masuda et al. (USPN 4,472,498).

EP 0139373 teaches an assay device and immunoassay that comprises:

- a multi-layer column having a chamber with a first end having a first aperture;
- a plurality of vertically stacked membrane layers stacked within the chamber with solid-phase substrates each carrying a different anti-analyte.

Swanson teaches an apparatus for the quantitative determination of an analyte in a liquid employs a liquid-permeable solid medium defining a liquid flow path sized to occupy substantially all of the cross-section of the chamber and engaging with the side of the wall to prevent the fluid sample from passing between the membrane layers and the wall of the chamber.

Neither EP '373 nor Swanson teach a multi-layer column comprising: membrane layers comprising a capture layer carrying anti-analyte and at least one light shielding layer coplanar with the capture layer, a light shielding layer including a light absorption sub-layer, a light shielding layer including a light reflection sub-layer

Masuda et al. teaches an analysis film comprising:

- membrane layers comprising a capture layer carrying anti-analyte and at least one light shielding layer coplanar with the capture layer (col.16, lines 28-47; col. 16, lines 48-53);
- a light shielding layer including a light absorption sub-layer (col. 16, lines 28-47; col. 16, lines 48-53);
- a light shielding layer including a light reflection sub-layer (col. 16, lines 28-47; col. 16, lines 48-53).

Mauda teaches that the capture layer can be for interfering analytes. It would have been obvious to modify the modified device of EP '373 to include a capture layer to remove interfering analytes.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the membrane layers of EP '373 by adding a light

shielding layer with a light absorption sub-layer or light reflection sub-layer coplanar to the capture layer because this addition of light shielding layer is used for blocking off the light incident through the spaces between the adjacent reflective layer or through coplanar capture layers. The addition of a light absorption sub-layer is obvious to use when a light incident is not wanted in the capture layer, and the light reflective sub-layer is obvious for the opposite, wanting light incident within the capture layer by reflection back to the capture layer.

Claims **8** and **9** are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0139373 A (Univ. California) in view of Swanson et al. (USPN 5,073,484) as applied to claim **1-3,16-19** above, and further in view of Greene et al. (USPN 5,391,478).

EP 0139373 teaches an assay device and immunoassay that comprises:

- a multi-layer column having a chamber with a first end having a first aperture;
- a plurality of vertically stacked membrane layers stacked within the chamber with solid-phase substrates each carrying a different anti-analyte.

Swanson teaches an apparatus for the quantitative determination of an analyte in a liquid employs a liquid-permeable solid medium defining a liquid flow path sized to occupy substantially all of the cross-section of the chamber and membrane layers engaging with the side of the wall to prevent the fluid sample from passing between the membrane layers and the wall of the chamber.

Neither EP '373 nor Swanson teach a multi-layer column that comprises: the solid-phase substrates carrying a blocking substance, all surfaces within the chamber carrying a blocking substance, and a buffer solution contained within the chamber.

Green et al. teaches an assay device and that comprises:

- a solid-phase substrate carrying a blocking substance to block non-specific binding (col 13, lines 42-46);
- all surfaces within the chamber carrying a blocking substance to block non-specific binding (col 13, lines 42-46);

It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify EP '373 to include a blocking substance to all surfaces within the chamber to insure that nonspecific binding on the membrane does not occur, this especially being the case when dealing with a sensitive assay, this procedure is common knowledge in the art of immunological assays.

Claim **13** is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0139373 A (Univ. California) in view of Swanson et al. (USPN 5,073,484) as applied to claim **1-3,16-19** above, and further in view of Bagshawe et al. (USPN 3,888,629).

EP '373 teaches an assay device and immunoassay that comprises:

- a multi-layer column having a chamber with a first end having a first aperture; a plurality of vertically stacked membrane layers stacked within the chamber with solid-phase substrates each carrying a different anti-analyte.

Swanson teaches an apparatus for the quantitative determination of an analyte in a liquid employs a liquid-permeable solid medium defining a liquid flow path which defines that the membrane layers are sized to occupy substantially all of the cross-section of the chamber and membrane layers engaging with the side of the wall to

prevent the fluid sample from passing between the membrane layers and the wall of the chamber.

Neither EP '373 nor Swanson teach an assay device that comprises a chamber with a waste reservoir in fluid communication with the second aperture of the chamber.

Bagshawe et al. teaches a reaction cell for the performance of immunoassay determination comprising:

- a reaction cell which has openings at both its upper and lower ends where it has enlargements or sockets to receive the lower and upper ends respectively of a separate upper tubular chamber and a separate lower tubular chamber (a waste reservoir) which is in fluid communication with the second aperture of the chamber (col. 2, lines 12-44);

It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify EP '373 to include a waste reservoir in communication with the second exit aperture in order to catch and properly dispose of the sample.

Claim **12** is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0139373 A (Univ. California) in view of Swanson et al. (USPN 5,073,484) as applied to claim **1-3,16-19** above, and further in view of Lechnitz (USPN 4,330,297).

- a multi-layer column having a chamber with a first end having a first aperture; a plurality of vertically stacked membrane layers stacked within the chamber with solid-phase substrates each carrying a different anti-analyte.

Swanson teaches an apparatus for the quantitative determination of an analyte in a liquid employs a liquid-permeable solid medium defining a liquid flow path which

defines that the membrane layers are sized to occupy substantially all of the cross-section of the chamber and membrane layers engaging with the side of the wall to prevent the fluid sample from passing between the membrane layers and the wall of the chamber.

Neither EP '373 nor Swanson teaches an assay device that comprises a chamber with a buffer solution in the chamber.

Leichnitz teaches a test tube for measuring nickel aerosols. The test tube comprises a buffer layer upstream of a reagent layer. The combination of buffer and reagent provides a detectable change with an analyte in the sample flowing through the test tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify EP '373 to include a buffer layer as taught by Leichnitz to ensure the sample produces a detectable change in a particular reagent layer.

Conclusion

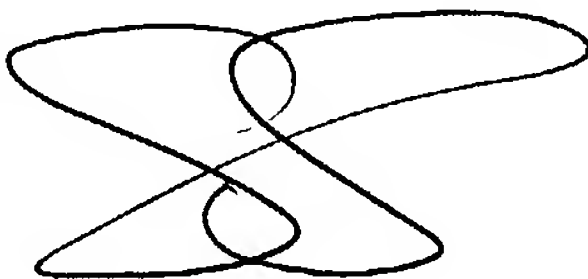
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke

June 21, 2004




Jill Warden
Supervisory Patent Examiner
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